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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/992,680 | 11/19/2001 | Chi-Huey Wong | 84503 | 1046 |

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| EXAMINER | |
|---|---|
| PRATS, FRANCISCO CHANDLER | |
| ART UNIT | PAPER NUMBER |
| 1651 | |

DATE MAILED: 12/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/992,680 | WONG ET AL. | |
| | Examiner | Art Unit | |
| | Francisco C Prats | 1651 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *17 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *21-51* is/are pending in the application.

4a) Of the above claim(s) *30-51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

**DETAILED ACTION**

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651.

Claims 21-51 are pending.

***Election/Restrictions***

Applicant's election without traverse of the group II invention, claims 21-29, in the paper filed July 10, 2003, is acknowledged. In view of the prior art discovered in the search process, the species election requirement of September 15, 2003, has been withdrawn.

Claims 30-51 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. As discussed immediately above, election was made **without** traverse in the paper filed July 10, 2003.

Claims 21-29 are examined on the merits.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, the recitation "reaction system" is indefinite because it is not clear what is being claimed. The language "system" suggests that the claims may be directed to an apparatus or device. However a "system" may also be construed as encompassing a simple composition of matter such as a solution, or even a process. Because it is not clear what subject matter is encompassed by the claims, a holding of indefiniteness is required. Note that the claims will be construed as reciting a solution comprising the enzymes enumerated in the claims.

Claim 26 is confusing to the extent it ultimately depends from claim 22 because applicant discloses the use of two separate GDP-fucose generating systems:

(1) one using the GDP-pyrophosphorylase coupled to PEP/pyruvate kinase-catalyzed ATP regeneration;

(2) the other generating GDP-fucose from GDP-mannose with an NADPH regenerating "system". The confusion lies in the fact that the dependency of claim 26 effectively mixes the two systems, whereas this does not appear to be consistent with applicant's disclosure.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 21-23 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bergh et al (U.S. Pat. 4,925,796) in view of Schachter et al (Methods Enzymol. 28:285-287 (1972)).

Bergh discloses compositions comprising a fucosyltransferase and GDP, for use in fucosylation of oligosaccharide moieties of glycoproteins. See column 18, lines 33-68; see also claim 25 at column 26. Bergh differs from the cited claims in failing to include the claimed GDP-fucose forming enzymes, fucose kinase and GDP-pyrophosphorylase, in his composition. However, Schachter clearly discloses that the GDP-fucose required in the fucosylation process of Bergh can be prepared using the very enzymes recited in the claims. Thus, solely looking to the cited prior art, the artisan of ordinary skill would have been motivated to have combined the fucosyltransferase of Bergh with the enzymes of Schachter so as to generate the GDP-fucose required for Bergh's fucosylation process. A holding of obviousness is therefore required.

Claims 21-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bergh et al (U.S. Pat. 4,925,796) in view of Schachter et al (Methods Enzymol. 28:285-287 (1972)), as applied to claims 21-23 above, and in further view of Demain et al (U.S. Pat. 4,178,210).

As discussed above, when taken in light of Schachter, Bergh renders obvious the compositions recited in claims 21-23 and 25. Neither Bergh nor Schachter discloses the presence of pyruvate kinase in their compositions as recited in claim 24. However, in view of the fact that Schachter's process requires ATP, the artisan of ordinary skill would have considered the use of the well-known PEP/pyruvate kinase ATP regeneration system an obvious method of regenerating the ATP required for the ultimate synthesis of the GDP-fucose required in Bergh's fucosylation process. See, e.g., Demain at column 4, lines 23-26 ("[t]he preferred phosphate donor is phosphoenolpyruvate and its corresponding phosphotransferase enzyme, pyruvate kinase.") Thus, the claimed use of pyruvate kinase in an enzymatic system known to require ATP must be considered obvious.

Claims 21-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bergh et al (U.S. Pat. 4,925,796) in view of Schachter et al (Methods Enzymol. 28:285-287 (1972)) and Demain et al (U.S. Pat. 4,178,210), as applied to claims 21-25, above, and in further view of Yamamoto et al (Agric. Biol. Chem. 48(3):823-824 (1984)).

As discussed above, when taken in light of Schachter and Demain, Bergh renders obvious the process recited in claims 21-

25. None of Schachter, Demain or Bergh discloses the presence of an NADPH regenerating system as recited in claim 26, or the GMP-mannose recited in claim 27, or the in situ generation of GDP mannose via the components recited in claims 28 and 29. However, Yamamoto clearly discloses that compositions comprising the claimed ingredients, including the NADPH regenerating system (right column, page 283, lines 18-21), result in the production of GDP-fucose from GDP-mannose. Moreover, Yamamoto discloses that the GDP-fucose so synthesized is suitable for use as a fucosyltransferase substrate. See first sentence page 285. Thus, the artisan of ordinary skill, recognizing that the GDP-fucose required in Bergh's process was suitably prepared using either Yamamoto's or Bergh's system, would have been motivated to have included the enzymes required for said syntheses in Bergh's fucosylation compositions. Moreover, the inclusion of a pyruvate kinase/PEP system in such a composition would have been obvious in view of the requirement for GTP in the synthesis of the GDP-mannose used by Yamamoto's system.

In sum, the claims recite an assembly of the enzymes known in the prior art to be useful in the synthesis of fucosylated oligosaccharides. The artisan of ordinary skill, recognizing solely from the prior art that the claimed combinations of enzymes were suitable in the preparation of fucosylated

oligosaccharides, clearly would have been motivated to have assembled the claimed ingredients into a single composition. Absent some demonstration of an unexpected result coming from the claimed combination, a holding of obviousness is clearly required.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 21-29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 11 of U.S. Patent No. 6,168,934. Although the conflicting claims are not of identical scope, they are not patentably distinct from each other. While certain embodiments of the claims under examination contain fewer

ingredients than the patented claim, the patented claim contains all of the ingredients recited in claims 21-24 and 28, under examination herein. Moreover, the patented claim suggests the presence of those intermediates and enzymes recited in the claims under examination. For example, although the patented claim does not recite the presence of GDP-mannose or GDP-mannose pyrophosphorylase, the presence of those species in the patented composition would be obvious in view of the fact that the patented composition would obviously generate the intermediate, and would require the pyrophosphorylase for the conversion from GMP-mannose to GDP-mannose. A terminal disclaimer is therefore clearly required.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 703-308-3665. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 703-308-4743. The fax phone number for the

organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Francisco C Prats
Primary Examiner
Art Unit 1651

FCP